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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/607,536 | 06/29/2000 | Earl A. Hubbell | AFFYP007X1C1 | 1335 |

26541 7590 12/20/2002
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| EXAMINER |
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FREDMAN, JEFFREY NORMAN

| ART UNIT | PAPER NUMBER |
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1637

DATE MAILED: 12/20/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/607,536

Applicant(s)

HUBBELL ET AL.

Examiner

Jeffrey Fredman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-10 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-10 and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 20, 2002 has been entered.

Specification

2. A substitute specification including claims is required pursuant to 37 CFR 1.125(a) because insufficient space was left at the top of the page to permit hole punching into the file jacket. Therefore, every page has text which is obscured by holes punched into them. While the examiner is able to examine the case, it will not be adequate for printing if the patent is issued.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

Claim Rejections - 35 USC § 112

3. Claims 8-10 and 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 26 are indefinite because the new limitation that "at least one of the polymer probes does not have the same actual sequence" conflicts with the earlier claim limitations that the "polymer probes having the same desired sequence will bind with a control sequence of monomers" and the limitation that the "polymer probes having the same desired sequence". On one hand, there is an express requirement that the probes are different in sequence and on the other hand, there is an express requirement that the probes have the same sequence. In view of this new 112, second paragraph rejection, this action will not be made final. Applicant is invited to rewrite the claim to clarify exactly the relationship of the probes in the claim. The 102 rejection over Socransky is maintained to the extent that the claim is indefinite over what is actually required. A new rejection over Chee is intended to address the limitation that the sequences differ, but can bind to the same control sequence.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 8-10 and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Socransky et al (Biotechniques (1994) 17(4):788-792).

Socransky teaches a substrate, which is a nylon membrane (page 788, column 2), with nucleic acid probes coupled onto the membrane (page 788, column 2) comprising:

a) a plurality of regions on the substrate in which diverse polymer probes are coupled in a checkerboard pattern, see page 789, figure 3, where it is clear that the interacting probes form a checkerboard pattern and for purposes of the rejection, the membrane after hybridization is the anticipatory product, since it has 43 regions loaded with different polymer probes (page 789, figure 3) and,

b) a plurality of regions on the substrate in which the polymer probes having the same sequence are coupled and the array also clearly has many regions in which polymer probes having the same sequence are coupled (page 789, figure 3). Thus, for example, the first column of the array has 43 different polymer probes and the entire column has the same sequence probe "371". The second column has 43 different polymer probes and the entire column has the same sequence probe "1219".

Finally, at least some of the plurality of regions are near the center of the substrate, and because "near" is a relative term as discussed in the 112, second paragraph rejection above, all of the regions might be "near" the center.

The limitation regarding the "polymer probes are formed with at least one different monomer addition cycle" simply represents "product by process" type limitations on the product. As MPEP 2113 notes "Product-by-process claims are not

limited to the manipulations of the recited steps, only the structure implied by the steps.” Here, where no particular structure is implied by the steps other than that the sequences are different in some way, the cited prior art meets the structural limitations of the claim.

6. Claims 8-10 and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Chee et al (U.S. Patent 5,837,832).

Chee teaches a substrate (column 6, lines 14-34, with nucleic acid probes coupled onto the membrane (see column 14, lines 14-34 and figure 26, for example) comprising:

a) a plurality of regions on the substrate in which diverse polymer probes are coupled in a checkerboard pattern, such as every overlapping 17 mer probe from exon 5 of the p53 tumor suppressor gene as well as four additional probes with each possible substitution at base 7 were also placed on the array (see figure 26 and column 23, lines 13-28) and,

b) a plurality of regions on the substrate in which the polymer probes having the same sequence are coupled and the array also clearly has many regions in which polymer probes having the same sequence are coupled, but where there are clearly sequences on the array that could bind to the same control monomer sequence but which are different in their actual sequence (see figure 26 and column 23, lines 13-28). For example, as shown in column 26, lines 45-50, when overlapping probes are made, they share all of their sequence but one nucleotide. Thus, the probes of Chee have probes which can bind to the same 16 mer target probe, since they share that entire

region, but which differ in actual sequence. Further, as noted in column 23, Chee expressly also places additional probes with each possible substitution. For each probe, one of these four probes will be identical to the wildtype, yielding a situation where two identical probes are paired. Figure 27 makes this perfectly clear. In the first row, where there is a T at the first position, the WT probe and the bottom probe would be identical, since both would have a T. There would be three different probes, which share 16/17 nucleotides, differing at position 7 with either an A, C, or G instead of a T. These would have been made with different monomer addition cycles and in any case, the products are not different however they are made.

Response to Arguments

7. Applicant's arguments filed November 20, 2002 have been fully considered but they are not persuasive.

Applicant argues the amendment that requires the polymer probes to have different actual sequences overcomes the prior art. As noted above, this limitation seems to conflict with other claim limitations, and in view of the indefiniteness the Socransky prior art rejection is maintained. If the claim were clarified, to definitively indicate that the sequences were different, then the Socransky rejection would be withdrawn. However, the newly applied Chee reference appears to address this new claim limitation. As noted above, this action is non-final.

Conclusion


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman
Primary Examiner
Art Unit 1637

December 19, 2002